REMARKS

Status of the Claims

Claims 1 and 61-75 are pending and stand rejected in the subject patent application. Claims 1 and 61 are amended with entry of the instant Response. Specifically, Claims 1 and 61 are amended to replace the recitation of "neoplasm" with "breast cancer." Support for the amendments is provided throughout the specification. Claim 61 is also amended to specify that the administered polypeptide is the polypeptide of SEQ ID NO:12. Claims 1 and 61 are further amended to delete redundancy in and improve clarity of the claim language.

Applicant notes that the claim amendments presented herein do not introduce new matter. Unless otherwise indicated, the amendments have been made to improve clarity or to expedite prosecution of the subject application, and should not be construed as acquiescence of any ground of rejections.

The following remarks address issues raised in the instant Office Action.

Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

The instant Office Action maintains the rejection of Claims 61-68, 73 and 75 as allegedly not complying with the written description requirement. The rejection appears to be directed to the recitation of "a polypeptide with the amino acid sequence of SEQ ID NO:12" in Claim 61 and the recitations of "is" in dependent Claims 66, 68, 73 and 75. Specifically, it is alleged in the Office Action that "'a polypeptide with the amino acid sequence of SEQ ID NO:12' reasonably reads on 'a polypeptide comprising the amino acid sequence SEQ ID NO:12'"

and that "the language 'is' encompasses the same meaning as the open language 'comprises'" (see, the Office Action, at page 2, last paragraph to page 3, first paragraph).

Applicant does not agree with the reasoning underlying the instant rejection. Nevertheless, in an effort to advance prosecution of the subject application, Applicant has amended herein Claim 61 which now specifies that the polypeptide to be administered is the polypeptide of SEQ ID NO:12. With regard to the recitation of "is" in Claims 66, 68, 73 and 75, Applicant notes that the recitation of "is" clearly indicates that the additional features recited in these dependent claims relate to a specific molecule, i.e., with close-ended scope. It simply defies common sense to assert, as stated in the instant Office Action, that the term "is" encompasses the same meaning as the open-ended term "comprises." Should the Examiner maintain the rejection on this ground, Applicant respectfully requests clarification.

In light of the above noted claim amendments and clarifications, Applicant submits that the currently pending claims are adequately described in the subject specification. Withdrawal of the instant rejection is therefore requested.

Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1 and 61-75 remain rejected as allegedly not enabled. The Examiner acknowledges that the specification enables methods for activating specific cytotoxic T lymphocytes in vivo in an animal having a breast cancer that overexpresses a Her-2/Neu protein and methods for treating breast cancer that overexpresses a Her-2/Neu protein. However, the Examiner appears to take the view that the claims are not enabled to the extent that the claims are directed to "neoplasm" rather than

just breast cancer or to administering a polypeptide with SEQ ID NO:12 rather than a polypeptide consisting of SEQ ID NO:12.

Applicant disagrees with the assertions set forth in the Office Action for maintaining the instant rejection. Nonetheless, in order to facilitate prosecution, Applicant has amended the claims herein to address these issues. As noted above, the claims as currently amended are directed to therapeutic methods for treating breast cancer. In addition, Claim 61 has been amended to more clearly indicate that the polypeptide to be administered in the methods is the polypeptide of SEQ ID NO:12. As such, the pending claims only encompass subject matter which has been indicated by the Examiner as enabled. Therefore, the instant rejection should be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The instant Office Action also maintains the rejection of Claims 1, 61-67 and 69-74 as allegedly being anticipated by Grey et al. (WO 94/20127). Applicant has previously pointed out that Grey et al. is not a proper 102(b) reference because Grey et al. was published on September 15, 1994, less than one year before the earliest priority date of the subject application, December 14, 1994. In the instant Office Action, the Examiner asks Applicant to provide evidence of the claimed priority date of the subject application.

The Examiner is advised that the filing transmittal dated March 26, 1999 indicates that the subject application is a divisional of parent application serial no. 08/860,232 filed June 13, 1997. The initial filing papers of the subject application also include a copy of the Declaration and Power of Attorney filed in the parent application. The latter clearly

indicates that the parent application is a national phase application of PCT application PCT/US/16415 (filed December 14, 1995) which further claims the benefit of priority to US application serial no. 08/355,558 which was filed on December 14, 1994. Thus, the subject application has a properly claimed priority date of December 14, 1994. Accordingly, the instant rejection should have been rendered under 35 U.S.C. § 102(a) instead of 35 U.S.C. § 102(b). Applicant provide the following remarks to traverse the instant rejection as if it had been made under 35 U.S.C. 102(a).

In maintaining the instant rejection, the Examiner reiterates the broad generic statement in Grey et al. which asserts, without actual evidence, that all the peptides discussed therein can be administered in a pharmaceutical composition to a patient to elicit a CTL response. Applicant has previously noted that such an assertion in Grey et al. does not constitute an enabling disclosure. Dismissing this issue as moot, the Examiner further asserts that a 102 rejection only requires that the claimed invention be so "described" in the prior art. Applicant cannot agree with this position. As explained previously, Grey et al. showed that a number of 9-mer and 10-mer peptides derived from several different proteins (e.g., HBV polymerase, p53 and c-ERB2) are able to bind to HLA-A2.1 with high affinity. One of the 10-mer C-ERB2 peptide has the same sequence as SEQ ID NO:12 of the subject invention ("peptide 1.0738"). However, Grey et al. only demonstrated CTL-inducing activities of several HBV-derived 9-mer peptides which bind to HLA-A2.1 with such affinity. Grey et al. does not examine CTL-inducing activities of any 10-mer peptides or any non-HBV peptides. However, Grey et al. nonetheless asserts that all of the peptides disclosed therein which are able to

bind to HLA-A2.1 would also be immunogenic (at page 76, lines 31-34). In other words, Grey et al. provided very limited experimental data on the CTL-inducing activities of a few HBV-derived 9-mer peptides but made very broad conclusion encompassing many other totally unrelated peptides.

As explained in Applicant's previously filed response, the broad conclusion in Grey et al. with respect to the other non-HBV peptides is both logically incorrect and scientifically flawed. Such a "description" certainly does not amount to an enabling disclosure which is required to sustain a rejection under 35 U.S.C. § 102. It is readily apparent that the unsubstantiated assertions in Grey et al. should not and could not preclude patentability of a potentially very large number of later inventions which disclose in an enabling manner CTL-inducing activities of the other non-HBV peptides. It would simply be unfair and unjustified to rely on the logically incorrect and scientifically flawed statements of Grey et al. to deprive patent protection of such later inventions.

The presently claimed invention is also novel and patentable over Grey et al. because Grey et al. does not teach or suggest each and every element of the claimed invention. The presently claimed invention (e.g., Claims 1 and 61) is directed to methods of employing the polypeptide of SEQ ID NO:12 to specifically activate CTLs in an animal having a breast cancer that overexpresses a Her-2/Neu protein or to treat subjects suffering from such a disease. Grey et al. at most may have showed that the 10-mer peptide 1.0738 is able to bind to HLA-A2.1 and that several unrelated 9-mer HBV peptides are able to induce a CTL response. Grey et al. does not teach in an enabling manner that peptide 1.0738 can be employed to specifically activate CTLs in an animal having a neoplasm that

overexpresses Her2/Neu, let alone a breast cancer that overexpresses Her2/Neu. Therefore, the presently claimed invention is not anticipated by Grey et al.

For all the reasons already on the record and reiterated herein, Applicant respectfully submit that the presently claimed invention is novel and patentable over the prior art and requests that the instant rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The instant Office Action additionally reject Claims 61-68 as allegedly being indefinite in reciting in Claim 61 "a polypeptide with the amino acid sequence" of SEQ ID NO:2. Applicant does not agree with the reasoning underlying this rejection. However, it is noted that this rejection is moot in view of the amendment to Claim 61 set forth above.

CONCLUSION

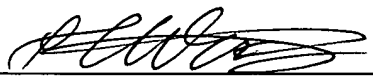
In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-784-2937. If there are any additional fees (or overpayments) associated with this Response, or any Response

associated with this application, the Director is hereby authorized to charge (or credit) our Deposit Account No. 19-0962.

Respectfully submitted,

Jan. 9, 2006
Date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